

REMARKS

Summary of Office Action

As an initial matter, Applicants note with appreciation that the Examiner has indicated consideration of the Second Supplemental Information Disclosure Statement filed July 6, 2006 by returning a signed and initialed copy of the Form PTO-1449 submitted therein.

Applicants also note with appreciation that the Examiner appears to have withdrawn all claim rejections set forth in the previous Office Action.

Claims 37, 38, 43 and 48-50 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Evans et al., U.S. Patent No. 5,358,752 (hereafter "EVANS") in view of Suzuki et al. U.S. Patent No. 5,145,781 (hereafter "SUZUKI"), and as evidenced by the entry in *Harrison's Principles of Internal Medicine*, 1994, New York, McGraw-Hill, Inc., 13th ed., pp. 309-313 (hereafter "HARRISON").

Claims 39-43, 44-47, 51-53, 55 and 56 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over EVANS in view of SUZUKI and as evidenced by HARRISON and further in view of N'Guyen et al., U.S. Patent No. 5,023,235 (hereafter "N'GUYEN I").

Claim 54 is rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over EVANS in view of SUZUKI and as evidenced by HARRISON and further in view of N'Guyen et al., U.S. Patent No. 5,114,716 (hereafter "N'GUYEN II").

Response to Office Action

Reconsideration and withdrawal of the rejections of record are respectfully requested in view of the following remarks.

Response to Rejection of Claims 37, 38, 43 and 48-50 under 35 U.S.C. § 103(a)

Claims 37, 38, 43 and 48-50 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over EVANS in view of SUZUKI and as evidenced by HARRISON. The rejection essentially alleges that EVANS teaches the topical application to skin of a composition comprising an antioxidant to control the oxidative damage of skin caused by UV radiation, that SUZUKI teaches that alpha-glycosyl rutin (which comprises alpha-glucosyl rutin) has properties as an antioxidant and is a UV absorbent and can be provided in pharmaceuticals and cosmetics, and that HARRISON teaches that excessive exposure to UVB radiation is implicated in the development of a number of skin disorders, including the immunosuppression of skin cells, wherefore the combined teachings of EVANS, SUZUKI and HARRISON allegedly render it obvious to one of ordinary skill in the art to use a flavonoid such as alpha-glucosyl rutin for the treatment or modulation of immunosuppression of skin cells induced by UVB radiation as recited in present independent claim 37.

Applicants respectfully traverse this rejection. In particular, there is no motivation to combine the teachings of EVANS and SUZUKI, let alone to combine these documents with HARRISON.

Applicants note that the rejection relies particularly on the abstract of EVANS according to which the phenolic diterpene compound of the ferruginol type disclosed {P29690 00083152.DOC}

therein (carnosic acid) can be incorporated in skin care products to reduce the accumulation of lipid peroxides and other biological oxidation products in the skin that result from sunlight, heat and radiation. SUZUKI mentions that alpha-glycosyl rutin, when used in pharmaceuticals, "acts as antioxidant to exhibit activities of removing activated oxygen and suppressing the formation of lipoperoxides" and that this "is convenient in the prevention and treatment of susceptive diseases and also in the maintenance and promotion of health." Col. 8, lines 19-25 of SUZUKI.

The only "link" between EVANS and SUZUKI identified by the Examiner appears to be the mentioning of the reduction of the accumulation of lipid peroxides by a phenolic diterpene compound of the ferruginol type in EVANS and the mentioning of the suppression of the formation of lipoperoxides by alpha-glycosyl rutin in SUZUKI. This "link" would allegedly motivate one of ordinary skill in the art to use alpha-glycosyl rutin (and specifically, alpha-glucosyl rutin) in the cosmetic compositions of EVANS (presumably in addition to or instead of the phenolic diterpene compound of the ferruginol type).

Applicants respectfully disagree with the Examiner in this regard. First, it is not seen that EVANS provides motivation to replace or supplement the phenolic diterpene compound of the ferruginol type specifically taught therein by any other antioxidant, let alone by a flavonoid such as alpha-glucosyl rutin. In this regard, it is pointed out that EVANS mentions that the use of antioxidants to inhibit peroxidation is well known and that a number of antioxidants have been used in cosmetic compositions, examples thereof being ascorbic/erythorbic acids and related compounds, tocopherols, BHA, BHT and hydroquinone. Col. 1, lines 30-37. Nevertheless, EVANS does <u>not</u> recommend the use of any of these well known and conventional antioxidants but teaches the use of <u>specific</u> (P29690 00083152.DOC)

antioxidants, i.e., carnosic acid and related compounds.

SUZUKI fails to teach or suggest that alpha-glycosyl rutin (alpha-glucosyl rutin) would be a better antioxidant than any of the conventional antioxidants whose use in cosmetic compositions is acknowledged by EVANS but not recommended for use in the compositions disclosed therein.

In particular, while SUZUKI mentions that alpha-glycosyl rutin (alpha-glucosyl rutin) "acts as antioxidant to exhibit activities of removing activated oxygen and suppressing the formation of lipoperoxides", this would appear to be a property which alpha-glycosyl rutin (alpha-glucosyl rutin) shares with many, if not all, antioxidants, including the conventional antioxidants specifically mentioned by EVANS.

Further, the activity of alpha-glycosyl rutin (alpha-glucosyl rutin) with respect to the removal of activated oxygen and the suppression of the formation of lipoperoxides is mentioned in SUZUKI only in the context of <u>pharmaceutical</u> compositions, not in the context of <u>cosmetic</u> compositions. For instance, only Examples B-10 and B-11 of SUZUKI (which describe <u>pharmaceutical</u> compositions for injection) mention the removal of activated oxygen and the suppression of the formation of lipoperoxides by alpha-glycosyl rutin whereas the Examples of SUZUKI which describe <u>cosmetic</u> compositions, i.e., Examples B-9, (B-13), B-14 and B-15, are silent in this regard.

Even further, even if one were to assume, *arguendo*, that one of ordinary skill in the art would be motivated to replace or supplement the phenolic diterpene compound of the ferruginol type used in the compositions of EVANS by alpha-glucosyl rutin, it is not seen that in this case HARRISON would render it obvious to employ a corresponding composition for the treatment or modulation of immunosuppression of skin cells induced (P29690 00083152.DOC)

by UV radiation. It is noted that in this regard the rejection relies on the mere statement in HARRISON that excessive exposure to UVB radiation is implicated in the development of a number of skin disorders, including the immunosuppression of skin cells.

Applicants are unable to see how such an extremely general and vague statement can render it obvious to one of ordinary skill in the art to use a composition which comprises alpha-glucosyl rutin for the treatment or modulation of immunosuppression of skin cells induced by UVB radiation. For example, HARRISON does not define which exposure to UVB radiation is "excessive" (for example, does sunbathing for an extended period of time which results in a sunburn qualify as "excessive" exposure or does regular and frequent exposure to sun which does not result in any immediately apparent adverse effects on the skin qualify as "excessive" exposure?).

HARRISON also merely states that this "excessive" exposure to UVB radiation is "implicated" in the development of, *inter alia*, immunosuppression of skin cells, i.e., that it is <u>speculated</u> (without scientific proof) that there is a possible link between the "excessive" exposure to UVB radiation and immunosuppression of skin cells. Further, according to HARRISON this assumed immunosuppression of skin cells "is believed" to lead to a "risk" of cancer development in human skin.

In other words, HARRISON does not provide any evidence whatsoever that someone who has been "excessively" exposed to UVB radiation would apply the composition of EVANS (with or without alpha-glucosyl rutin) and thereby (necessarily) treat or modulate the immunosuppression of skin cells induced by UV radiation.

Applicants submit that at least for all of the foregoing reasons, the rejection of claims 37, 38, 43 and 48-50 under 35 U.S.C. § 103(a) over EVANS in view of SUZUKI and as (P29690 00083152.DOC)

evidenced by HARRISON is without merit and should be withdrawn, which action is respectfully requested.

Response to Rejection of Claims 39-43, 44-47, 51-53, 54, 55 and 56 under 35 U.S.C. § 103(a)

Claims 39-43, 44-47, 51-53, 55 and 56 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over EVANS in view of SUZUKI and as evidenced by HARRISON and further in view of N'GUYEN I. Claim 54 is rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over EVANS in view of SUZUKI and as evidenced by HARRISON and further in view of N'GUYEN II.

Applicants respectfully traverse these rejections as well. Applicants note that claims 39-43, 44-47 and 51-54 are dependent, directly or indirectly, from claim 37. Since N'GUYEN I and N'GUYEN II clearly do not cure the deficiencies of EVANS, SUZUKI and HARRISON set forth above, the subject matter of claims 39-43, 44-47 and 51-54 is not rendered obvious by the cited documents for at least all of the reasons set forth above with respect to claim 37.

Independent claim 55 recites, *inter alia*, all of the features recited in claim 37, wherefore the subject matter of claim 55 (and that of claim 56 dependent therefrom) is likewise not rendered obvious by the cited documents for at least all of the reasons set forth above with respect to claim 37.

In view of the foregoing, Applicants refrain from commenting on the various allegations set forth in the present Office Action with respect to the alleged teaching provided by the combination of EVANS, SUZUKI, HARRISON and N'GUYEN I or

N'GUYEN II. However, Applicants' silence in this regard must by no means be construed as Applicants' admission that any of these allegations is meritorious.

CONCLUSION

In view of the foregoing, it is believed that all of the claims in this application are in condition for allowance, which action is respectfully requested. If any issues yet remain which can be resolved by a telephone conference, the Examiner is respectfully invited to contact the undersigned at the telephone number below.

> Respectfully submitted, Ghita LANZENDORFER et al.

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